



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

3731/15
12-24-03

In re the Application of **Halseth**

Application No. 09/619,901

Attorney Docket No. 1032-P00101US9

Filed: July 19, 2000

For: Medical Devices with Retractable
Needle

Examiner: Serke, C.

Group Art Unit: 3731

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TECHNOLOGY CENTER R3700

RESPONSE TO OFFICE ACTION

In an Official Action dated June 4, 2003, the Examiner rejected the claims as obvious over a combination of several various elements of several different references. Applicants request that the Examiner reconsider the rejection in light of the following discussion.

In the Official Action, the Examiner recognizes that the prior art does not disclose a device having an add-on needle assembly in which the needle can be retracted into the plunger after use. The Examiner tries to fill this shortcoming with Alberts 4,906,236. However, this combination ignores the combined teaching of the references. Alberts simply teach as add-on needle assembly in which the needle is advanced from the needle assembly and then subsequently retracted into the needle assembly. There is no teaching or suggestion in Alberts that the structure could ever be modified to be used for retracting a needle into the barrel of the syringe, let alone into the plunger after use.

In addition, Alberts specifically teaches that it is desirable to keep the elements of the needle attached together. See col. 4 lines 60-65. Therefore, Alberts specifically

teaches away from a structure in which the parts are separated during use. Therefore, Alberts teaches away from the combination that the Examiner suggests, since the combination would result in the needle being separated from other parts of the needle assembly. Furthermore, Alberts is directed to a simplified structure that can be used with existing syringes. See col. 1 lines 29-40. Since Alberts teaches away from a more complicated device, Alberts teaches away from a more complicated structure as suggested by the Examiner. Therefore, since Alberts teaches away from the proposed combination, there is no motivation to combine the references as suggested by the Examiner.

The Federal Circuit has repeatedly emphasized the importance of showing evidence of a motivation to combine the prior art references in the manner suggested. It is not enough to say that one would or could combine references in a particular way. It is the Examiner's burden to provide "actual evidence" of the motivation. In re Dembiczak, 50 U.S.P.Q. 2d 1614,1617 (Fed. Cir. 1999). According to the Federal Circuit:

Combining prior art references without evidence of a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blue print for piecing together the prior art to defeat patentability—the essence of hindsight.

Id.

In In re Dembiczak, the inventor had created a trash bag made of orange plastic and decorated with lines and facial features, so that when the bag was filled it resembled a jack-o-lantern. The Examiner erroneously combined a conventional prior art plastic trash bag with an article teaching the construction of stuffed paper bags decorated to look like jack-o-lanterns. The combination was erroneous because there was no teaching in the references to modify the teachings in the way that the inventor

had so done. The fact that both references were directed to bags was not enough. Why would someone think to combine features of a large orange trash bag and a small decorated arts and crafts paper bag?

Similarly, the Examiner appears to combine bits and pieces from Shaw, Alberts, Allard and Ridderheim just because they are all directed to safety needle devices. However, as discussed above, rather than supporting the Examiner's combination, the references actually teach reasons for not combining in the manner suggested by the Examiner. Accordingly, Applicants request that the Examiner reconsider the rejection of claims 45-73.

In fact, if the Examiner is going to pick and choose elements from the various patents in the safety needle field, simply because the different patents are needle-bearing devices, the PTO may as well close the category. The needle-bearing field is like many other fields in which the inventiveness comes from combining known elements in an unknown manner. In fact, there are very few devices in the mechanical field in which unknown elements are used. Most every patent in the mechanical field is based on a new combination of known elements. That is exactly why it is so important for the Examiner to scrutinize the motivation to combine different references. It is easy to re-create a device out of known parts after you are told the final structure. But the point is: in light of the prior art, would you think to make the combination that the inventor did when he or she invented the new structure? That is a difficult question to answer after you already know the final result. Again, that is why the Federal Circuit has continuously demanded that the Examiner provide actual evidence of a motivation to combine.

Finally, in addition to the reasons set forth above, the combination suggested by the Examiner is not proper because the Shaw reference is not prior art against the present application. Shaw was filed in September of 1995 claiming priority

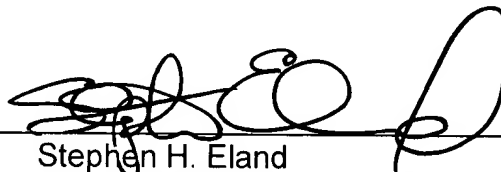
to an application filed in May of 1995. The present application claims priority to applications that go back to 1989. Since Shaw was filed years after the priority dates for this application, Shaw is not prior art against this application. For this additional reason, Applicants request that the Examiner reconsider the rejection of claims 45-73.

In light of the foregoing, Applicant believes that this application is in form for allowance. The Examiner is encouraged to contact Applicant's undersigned attorney if the Examiner believes that issues remain regarding the allowability of this application.

Respectfully submitted,

DANN, DORFMAN, HERRELL & SKILLMAN
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Attorneys for Applicant(s)

By

A handwritten signature in black ink, appearing to read 'Stephen H. Eland', is written over a horizontal line.

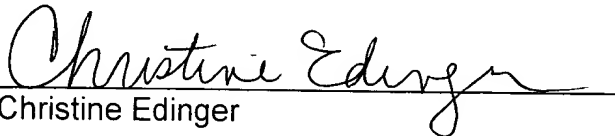
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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this Response and accompanying papers are being deposited on **December 4, 2003** with the United States Postal Service as first-class mail in an envelope properly addressed to Commissioner for Patents, Alexandria, VA 22313-1450.

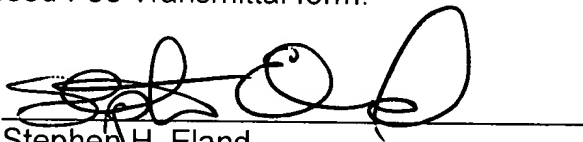
December 4, 2003
Date of Certificate


Christine Edinger

Petition for Extension Under 37 CFR §1.136(a)

Applicant's undersigned Attorney hereby petitions for an extension of time of **THREE** months beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

December 4, 2003
Date of Certificate


Stephen H. Eland
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